**DETAILED ACTION**

The amendment filed 1/16/2008 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 4-5 and 7 have been canceled.

2. Claim 1 has been amended.

3. Remarks drawn to objections and rejections under obviousness-type double patenting, 102(b) and 103.

Claims 1-3 and 6 are pending in the case.

The objection to the abstract has been overcome by amendment.

The rejection of claims 4 and 7 under 35 USC 102(b) as being anticipated by Balazs et al (Radiation Research, 1959, 11, 149-164) and the rejection of claim 5 under 35 USC 103(a) as being anticipated by Balazs et al (Radiation Research, 1959, 11, 149-164) have been withdrawn since said claims are canceled.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claim 1 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,091,337 ('337) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that claim 1 of '337 is directed to a process of depolymerization of glycosaminoglycans comprising irradiating with high energy radiation in the presence of an organic compound. Instant claim 1 has been amended and is now directed to a process for depolymerization of heparin wherein the process results in at least 50% reduction in molecular weight via exposure to UV radiation. The claimed process does not include any addition of organic compound as required in claim 1 of '337.

Applicants' arguments are not found to be persuasive.

Instant claim 1 recites the term comprising, which does not exclude other material like organic compound being present in the process. Instant claim 1 recites irradiation with UV rays. This reads on high energy irradiation as recited in claim 1 of '337. Claim 1 of '337 is drawn to depolymerization of glycosaminoglycan (glycosaminoglycan can be heparin) and does not recite any specific molecular weight or a range for the depolymerized product. This means that the molecular weight can be anything as long as it is less than the molecular weight of the starting glycosaminoglycan. This reads on the recitation of instant claim 1, which is also drawn to depolymerization.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1-3 and 6 under 35 U.S.C. 102(b) as being anticipated by Balazs et al (Radiation Research, 1959, 11, 149-164; document # CA in IDS of 11/07/2005) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that:

1. Hyaluronic acid is depolymerized at a much faster rate than heparin when exposed to UV radiation (as taught by Balazs). Specific viscosity of hyaluronic acid decreases rapidly to near zero after less than 20 minutes. This according to Balazs is an indication of rapid degradation of the polysaccharide. No such data relating to reduction in viscosity or molecular weight is presented or discussed by Balazs for heparin.

2. The results presented in Figure 2 of Balazs indicate that the molecular weight of heparin is decreased only slightly after exposure to radiation that completely destroys hyaluronic acid. As seen in Figure 2, the percentage of anticoagulant activity data for heparin shows only slight decrease and leveling off after 80 minutes of irradiation. It is well known that the percentage of anticoagulation activity of heparin is directly related to the level of depolymerization i.e., as depolymerization progresses anticoagulation activity of heparin also decreases. As seen in Fig. 2, after irradiation for 120 minutes an approximate 25% reduction in

anticoagulation activity is seen. This means that the molecular weight of heparin has not been reduced to anywhere near 50%.

Applicants' arguments have been considered but are not found to be persuasive.

Balazs et al also teach that similar results were obtained on irradiating heparin with UV light (page 155, last paragraph). Perusal of Figure 2 of Balazs shows that the anticoagulant activity of heparin is down to 63% approximately and not 75% as stated by the applicants (the curve with x) and the corresponding reduction for hyaluronic acid is close to 50%. Applicants state that it is well known in the art that the percentage of anticoagulation activity of heparin is directly related to the level of depolymerization and that the viscosity decrease seen for heparin does not correspond to a 50% decrease in molecular weight. This is just a conclusionary statement by the applicants. Applicants have not provided any supporting evidence for their statement that the percentage of anticoagulation activity of heparin is directly related to the level of depolymerization. Even though UV irradiation has different effects on hyaluronic acid and heparin it doesn't necessarily mean that the molecular weight reduction in the case of heparin is more than 50% compared to that of the starting material. It cannot be concluded, as applicants have done, that the percentage reduction in viscosity disclosed for heparin by Balazs is indicative of molecular weight reduction that is nowhere close to 50% as instantly claimed.

***Conclusion***

Claims 1-3 and 6 are rejected

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623